UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD L. DUNN and CODY L. YARBOROUGH

Appeal 2008-0294
Application 10/634,656[1]
Technology Center 3700

Decided: 10 December 2007

Before JAMESON LEE, SALLY C. MEDLEY and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

MEDLEY, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Application for patent filed 05 August 2003. The real party in interest is QLT USA, INC.

A. Statement of the Case

This is an appeal under 35 U.S.C. § 134 from the Examiner's Final Rejection of claims 1-14. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Kanno	4,629,455	Dec. 16, 1986
Chu	4,743,229	May 10, 1988

Claims 1-14 stand rejected as being unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno.

BACKGROUND

The invention is related to a system for joining two syringes for the purpose of mixing and preparing therapeutic compositions. The system includes a first syringe **13** with a male end portion **10** with a locking ring **11** and tip **8** and a second syringe **14** with a female end portion **27**. The female end portion has one or more protruding members **30** adapted to detachably fit the locking ring and an opening that is adapted to receive the tip of the male end portion. The locking ring couples the first and second syringe when the tip of the male end portion is disposed within the opening of the female end portion. (Abstract, Spec. pp. 4-5 and **figs. 1, 3-4**).

B. Issues

The issue before us is whether Applicants have shown that the Examiner erred in determining that claims 1-14 are unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno?

For the reasons that follow, Applicants have failed to sufficiently show that the Examiner erred in determining that claims 1-14 are unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno.

C. Findings of Fact ("FF")

The record supports the following finding of facts as well as any other findings of fact set forth in this opinion by at least a preponderance of the evidence.

1. Applicants' claims 1-14 are the subject of this appeal.
2. Claims 2-14 are dependent on independent claim 1.
3. Claim 1 is representative and is as follows:

> A coupling syringe system comprising:
> a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip, the first syringe barrel having a first syringe inner surface;
> a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with the first syringe inner surface;
> a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring, the second syringe barrel having a second syringe inner surface;
> a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with the second syringe inner surface;
> the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein;

> wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement.

4. The Examiner found that Chu describes a coupling syringe system having a first syringe **12** including a first syringe barrel **16** having a first syringe open proximal end **20**, a first syringe distal end **18**, a first syringe tip with a male end portion, locking ring **42**, tip, a first syringe inner surface **56**, a first syringe plunger **40**, a second syringe **14**, a second syringe barrel **22**, a second syringe open proximal end **26**, a second syringe distal end **24**, second syringe tip **50** with a female end portion, exteriorly protruding members **52** adapted to detachably fit the locking ring **42**, a second syringe inner surface **58**, and a second syringe plunger **32**, where the female end portion has an opening therein that is configured and sized to receive the tip of the male end portion therein, where the locking ring couples the first syringe to the second syringe when the male end portion is disposed within the female end portion, forming a fluid tight engagement (**figs. 1-3**; Final Rejection p. 2 and Ans. pp. 3-4).

5. The Examiner found that Chu does not teach a rotatably coupled locking ring mounted on a medical instrument (Final Rejection p. 2 and Ans. p. 5).

6. The Examiner found that Kanno describes a rotatably coupled locking ring mounted on a medical instrument (Final Rejection p. 2 and Ans. p. 5).

7. The Examiner found that Kanno describes a connector system having a male end portion **12** adapted to be inserted into the female end

portion **13**, where the locking ring **17** is rotatably coupled to the male end portion (**fig. 3**; Ans. p. 5).

8. The Examiner also found that Kanno describes disadvantages of a locking ring monolithically formed to the male end portion (**fig. 1** and col. 1, ll. 19-38; Ans. p. 5).

9. The Examiner concluded that it would have been obvious to one with ordinary skill in the art at the time of the invention to have modified the connecting structure of Chu with the connecting member as taught by Kanno for the well known purpose of providing a male and female connection alternative that can be joined firmly with high reliability (Final Rejection p. 2).

10. The Examiner also concluded that it would have been obvious to one of ordinary skill in the art to modify the invention of Chu by having the locking ring rotatably coupled to the male end portion as suggested by Kanno in order to provide a connection assembly that is reliable and prevents drug loss due to a faulty connection, thereby resulting in a mixture that may not be properly combined (Ans. p. 5).

11. Applicants describe that the first syringe can alternatively be manufactured by independently molding the syringe **13** and locking ring **11** and then mounting the locking ring **11** and first syringe **13** (**fig. 2** and Spec. p. 9).

12. Applicants disclose it is preferable for the locking ring **11** to be permanently attached to the first syringe **13** and can be typically attached by welding the two pieces together (**fig. 2** and Spec. pp. 9-10).

13. Applicants also disclose the locking ring **11** can also be mounted coaxially and rotatably with tip **8** by a flange and seal configuration where

the locking ring **11** can be rotated around the tip **8** (**figs. 2, 4** and Spec. pp. 9-10).

D. Principles of Law

"In the patentability context, claims are to be given their broadest reasonable interpretations" and "limitations are not to be read into the claims from the specification" *In re Van Geuns,* 988 F.2d 1181, 1184 (Fed. Cir. 1993).

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, (1966). *See also KSR*, 127 S.Ct. at 1734 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.") The Court in *Graham* further noted that evidence of secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, etc., "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham,* 383 U.S. at 18.

In *KSR*, the Supreme Court explained that despite the enactment of Section 103 and the *Graham* analysis there still remains "the need for caution in granting a patent based on the combination of elements found in

the prior art." 127 S.Ct. at 1739. Based on its precedent, the Court reaffirmed the principle that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.*

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. [A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Id. at 1740.

The Court's opinion in *United States v. Adams*, 383 U.S. 39, 40 (1966) is illustrative of the application of this principle in the case where the claimed invention is a prior art structure altered by substituting one element in the structure for another known element. *Id.* at 1739-40. "The Court [in *Adams*] recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *Id* at 1740 (citation omitted) (The Court ultimately found unexpected results resulting from prior art warnings to be dispositive of nonobviousness).

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of

> course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.

In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

E. Analysis

Claims 1-8, 10-11 and 13-14

Applicants argue that the Examiner has failed to establish a prima facie case of obviousness because neither Chu nor Kanno show the following limitations of claim 1:

- "a first syringe including ... a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip"
- "a second syringe including ... a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring"
- "the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein" and
- "wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement." (App. Br. p. 12).

Applicants' argument is conclusory and not meaningful. Merely copying the language of a claim, highlighting certain limitations, and concluding that a reference does not meet the highlighted limitations is not helpful to the trier of fact and certainly does not rise to the level of showing error in the Examiner's findings.

The shaded portions in figure 1 below which is reproduced from figure 3 of the Chu reference more explicitly illustrate the first syringe tip with a male end portion and locking ring.

Figure 1 is below:

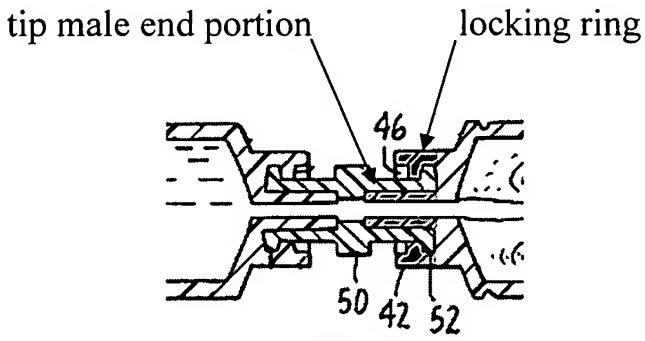

Fig. 1

Figure 1 depicts the connection between the first and second syringe as shown in figure 3 of Chu and includes additional shading to highlight the first syringe tip male end portion and locking ring.

The shaded portions in figure 2 below which is reproduced from figure 3 of the Chu reference more explicitly illustrate the second syringe tip female end portion and exteriorly protruding members **52**.

Figure 2 is below:

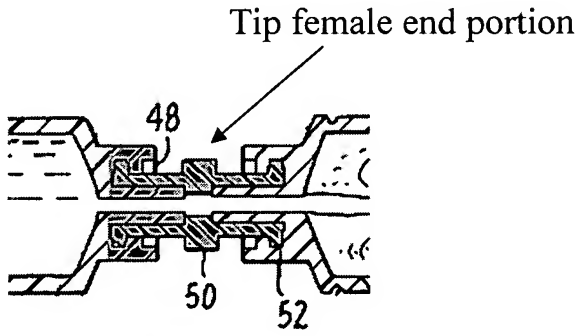

Fig. 2

Figure 2 depicts the connection between the first and second syringe as shown in figure 3 of Chu and includes additional shading to highlight the second syringe tip female end portion and exteriorly protruding members **52**.

Figures 1 and 2 further show the female end portion has an opening sized and configured to receive the tip of the male end portion and the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion and forms a fluid tight engagement. The way we view it, and as applied by the Examiner, the connector **50**, when connected, forms part of the second syringe **14**. In other words, the syringe **14**, when connected to connector **50,** will function as a syringe to draw and eject liquids.

Applicants argue that Chu shows a separate connector that isn't integrated with the first or second syringe, whereas Applicants' claimed invention does not require a separate connector (App. Br. p. 12). Applicants also appear to argue that their use of the word "including" in claim 1 requires the structure of the connector to be integral with the syringe and that the claim language defines a "direct structural relationship" (Reply Br. pp. 2, 4).

At first blush, Applicants' argument has some appeal to it. If the Chu connector 50 impeded the function of the Chu syringe **14** when connected, then the Examiner's position may not have merit. But that is not the case. The Chu syringe **14** when connected to connector **50** structurally and functionally results in the claimed second syringe. We understand Applicants' described preferred embodiment is a syringe with an integrated connector on the end. However, claim 1 does not require a connector integral with either of the syringes, a direct structural relationship, nor the foreclosure of the use of separate parts to form either the first or second syringe.

Applicants' argument that the complete claim language requires "that the first syringe includes a structurally related tip with a male end portion and the second syringe includes a structurally related tip with a female end portion, and further including the structural interrelationship that the first syringe and second syringe directly couple to one another" is also not persuasive (Reply Br. pp. 2-3). Claim 1 does not require either of the syringes to have "a structurally related tip", whatever that may mean, nor a direct coupling between the syringes. Applicants' request for us to narrowly interpret the word "including" to mean that the syringe and connector must be one unitary piece[2] or for us to import limitations from the specification into the claims is not commensurate with our duty to give claims their broadest reasonable interpretation[3] while also not reading limitations into the claims from the specification.[4] For all of these reasons, Applicants have not demonstrated error in the Examiner's finding that the Chu connector **50** as it is connected to the second syringe **14** corresponds to the claimed female end portion (Final Rejection p. 3 and Ans. pp. 5-6). Applicants have not disputed the Examiner's findings with respect to the remaining limitations of claims 1-8, 10-11 and 13-14. As a result, the Examiner has found in the Chu reference alone "each and every element as set forth in the claim[s]"[5] sufficient to support a rejection for anticipation under 35 U.S.C. § 102 (FF

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[2] Cf. *In re Morris*, 127 F.3d 1048, 1055 (Fed. Cir. 1997), in which "*integrally* formed as a portion of" (emphasis added) was read to be broader than "fused together". Applicants are in an even weaker position in this case, since "including" is less indicative of a unitary construction than "integral".

[3] *In re Van Geuns* 988 F.2d 1181, 1184 (Fed. Cir. 1993).

[4] *Id.*

[5] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

4). As such, the Examiner has established a prima facie case of obviousness since anticipation is the "epitome of obviousness"[6].

For these reasons we find that Applicants have failed to sufficiently show that the Examiner erred in determining that claims 1-8, 10-11 and 13-14 are unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno.

Claims 9 and 12

Claims 9 and 12 both recite the further limitation "wherein the locking ring is rotatably coupled with the male end portion." In rejecting the claims, the Examiner relied on Kanno for teaching a rotatable locking ring coupled with the male end portion (FFs 5-7). The Examiner concluded that the modification of the Chu connecting structure with the connection member of Kanno was obvious in order to provide a male and female connection alternative that can be joined firmly with high reliability (FFs 9-10). Applicants argue there is no teaching, suggestion or motivation to combine the references as required by *In re Lee*[7] (App. Br. pp. 10, 16). The Supreme Court has explicitly rejected the Federal Circuit's rigid application of the "teaching, suggestion or motivation" (TSM) test to the determination of obviousness as inconsistent with their expansive and flexible approach and precedents[8]. The Court reaffirmed the principle set out in *US v. Adams*[9] that "when a[n] [application] claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." As

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[6] *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982).
[7] 277 F.3d 1338 (Fed. Cir. 2002).
[8] *KSR*, 127 S.Ct. at 1739, 1741.
[9] 383 U.S. 39, 50-51 (1966)

pointed out by the Examiner, Kanno describes the disadvantages of a non-rotatable locking ring in the prior art (FF 8). Kanno describes that a non-rotatable locking ring will not allow the angle and position of connection in the relative rotational directions around their axes to be selected at will at the time the connector members are joined to each other, and the connectors are sometimes loosened (Col. 1, ll. 31-38). Kanno describes that male and female connectors with a rotatable locking ring can be joined firmly with high reliability (col. 1, ll. 6-9; col. 2, ll. 63-68 and col. 7, ll. 7-11), which is precisely the language that the Examiner used in concluding that the claimed invention was obvious (FF 9). Kanno also describes a locking ring that is rotatable about the male connector member that enables the angle and position of the male and female connector in their relative rotational directions about their axes to be selected at will (col. 1, ll. 57-63; col. 6, ll. 17-25 and col. 7, ll. 7-11), thus overcoming the prior art disadvantages. Applicants have failed to demonstrate error in the Examiner's determination that if the locking ring of Chu **42** was modified with the rotatable locking ring **17** of Kanno, the combination would yield the predictable result of ensuring a highly reliable and firm joining of connectors while also allowing the angular position of connection between the connectors to be freely selected.

Applicants also argue that Chu teaches away from being combined with and or modified by Kanno because the object of Chu's invention is to provide a device that is structurally simple and inexpensive to construct (App. Br. p. 17 and Chu col. 2, ll. 58-60). Applicants infer from Kanno's recitation of a rib **22** having a limited thickness that Kanno recites a rib requiring precise and expensive tolerancing which is in opposition to Chu's

objectives (**fig. 4**; App. Br. p. 17). However, Kanno merely describes a limited range of thickness for the rib (i.e. the rib can be 0.15mm or 1.50 mm or any thickness in between). Applicants have failed to direct us to evidence or even where in Kanno that the manufacture of the rib requires precise or expensive tolerancing. Applicants' assertions are in the form of attorney argument and are unpersuasive. Argument of counsel cannot take the place of evidence lacking in the record[10]. As a result, we do not find Kanno to teach away from the invention because a person of ordinary skill in the art upon reading Kanno would not "be discouraged from following the path set out in the reference, or . . . led in a direction divergent from the path that was taken by the applicant."[11]

For all these reasons we find that Applicants have failed to sufficiently show that the Examiner erred in determining that claims 9 and 12 are unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno.

Decision

Upon consideration of the record, and for the reasons given, the Examiner's rejection of claims 1-14 as unpatentable under 35 U.S.C. § 103(a) over Chu in view of Kanno is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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[10] *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA); *see also In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).
[11] *Gurley*, 27 F.3d at 553.

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